enacted the MMA's declaratory judgment provision to ensure that "courts will find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies." (H.R. CONF. REP. NO. 108-391, at 836, App. 82a-83a). As discussed below, the Federal Circuit's ruling has the perverse effect of allowing brand companies to delay infringement litigation and, as a result, the market entry of much-needed affordable generic drugs. To effectuate that Congressional intent here, and to prevent judicial nullification of the MMA's declaratory judgment provision, it is critical for this Court to review the Federal Circuit's decision to confirm that the reasonable apprehension test is *not* coextensive with the "case or controversy" requirement of Article III, as the Federal Circuit held.

B. The Federal Circuit's decision permits brand companies like Pfizer to manipulate the statutory scheme to their benefit.

Rather than carrying out Congress' goal of ending brand company abuse of the generic approval system, the Federal Circuit's decision allows brand companies to continue manipulating Hatch-Waxman to serve their purposes.

1. Congress recognized that early resolution of patent disputes is key to expediting generic market entry.

Before the 1984 Hatch-Waxman Amendments, any company that manufactured or used a patented drug while compiling the data necessary to complete an application for FDA approval of a generic drug could be sued for infringement. *See Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 861 (Fed. Cir. 1984) ("*Bolar* decision"). As a result, a generic company had to wait until the patent protecting a drug product expired before it could even begin the lengthy process of preparing its application for submission to the FDA. And because such testing can, and

often does, take years, the brand company continued to monopolize that particular drug market years *after* patent expiration as the generic company worked to complete the necessary tests and waited for FDA approval. This unintended period of extended market exclusivity often was referred to as a *de facto* patent term extension. *See generally* Susan Kopp Keyack, *The Drug Price Competition and Patent Term Restoration Act of 1984: Is It a Healthy Long Term Solution?*, 21 RUTGERS L.J. 147, 153-54, 160-61, 165 (1989); Jonathan L. Mezrich, *The Patentability and Patent Extension of Lifesaving Drugs: A Deadly Mistake*, 6 J.L. & HEALTH 111, 115-16 (1991/1992).

Hatch-Waxman included a series of statutory provisions designed to speed generic market entry by eliminating the *de facto* patent extension. Congress did away with the *Bolar* decision, exempting the manufacture and/or use of patent-protected drugs from the conventional law on patent infringement, when done for the purpose of preparing an ANDA. *See* 35 U.S.C. § 271(e)(1). This exemption allows the generic company to prepare its ANDA *before* patent expiry, thus furthering Congress' goal of getting generic drug products on the market quickly.

Congress also created a mechanism for litigating patent disputes while the FDA substantively reviews an ANDA. Specifically, Congress required brand companies to submit the number of any patent that "claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(c)(2) *see also id.* § 355(b)(1). The FDA publishes this patent information in the Orange Book. 21 U.S.C. § 355(b)(1), (c)(2), (j)(7)(A); 21 C.F.R. § 314.53(e).

Congress then provided that filing an ANDA seeking FDA approval to market a drug prior to the expiration of a

patent listed in the Orange Book constitutes a statutory act of patent infringement. *See* 35 U.S.C. § 271(e)(2). With this statutory scheme, Congress "create[d] case-or-controversy jurisdiction to enable the resolution of an infringement dispute before the ANDA applicant has actually made or marketed the proposed product." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003) (citation omitted); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) ("Quite obviously, the purpose of subsection[] (e)(2) . . . is to enable the judicial adjudication upon which the ANDA . . . scheme[] depend[s]."); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) (stating that filing an application seeking FDA approval prior to patent expiration is an "act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity"); *In re '639 Patent Litig.*, No. 97-12416-RCL, 1999 WL 528806, at *1 n.1 (D. Mass. June 15, 1999) (recognizing that Congress "create[d] a case or controversy sufficient to satisfy Article III so that the federal court may exercise its jurisdiction to quickly resolve any disputes concerning a patent claim's validity, enforceability, and/or infringement").

Congress did not design Hatch-Waxman as one-sided legislation in favor of generic drug companies. In the legislation, formally titled the Drug Price Competition and Patent Term Restoration Act of 1984, Congress struck a carefully-crafted balance between protecting legitimate patent rights (thus encouraging innovation) and promoting early generic market entry (thus saving the public money). To that end, the legislation included several provisions designed to benefit brand companies. For example, Congress extended the life of certain pharmaceutical patents (*see* 35 U.S.C. § 156) and included provisions that prevent FDA from approving a generic drug application for 30 months in cases where the patentee commences a patent infringement suit within 45 days after receiving notice of the

generic applicant's desire to seek FDA approval prior to patent expiration (*see* 21 U.S.C. § 355(j)(5)(B)(iii)).

Despite Congress' intent, brand companies found ways to manipulate the system, thereby unduly delaying generic competition and market entry. One delay tactic involved brand companies obtaining and listing patents, but refusing to bring suit when confronted with a generic applicant seeking immediate approval. While perhaps seeming counterintuitive, brand companies found that delaying suit could, in fact, delay generic market entry. This case presents a classic example of such a situation.

Here, Pfizer would have derived no benefit from triggering the 30-month stay of FDA approval of Teva's ANDA by filing suit against Teva on the '699 patent because the other listed patent, U.S. Patent No. 4,356,518 ("the '518 patent"), prevented Teva from going to market until 2006, which is more than 30 months from the date that Teva filed its ANDA in 2002. Specifically, had Pfizer brought suit on the '699 patent immediately, it merely would have given Teva a chance to prove that the '699 patent was invalid or not infringed before the expiration of the '518 patent and, thus, the chance to market immediately upon expiration of the '518 patent. On the other hand, prolonging Teva's uncertainty with respect to its liability under the '699 patent promised to delay Teva's market entry until after the expiration of the '518 patent.

The reason Teva would delay launch is a matter of simple economics. Infringement damages calculated on the basis of the enormous monopoly profits associated with blockbuster drugs, such as Zoloft®, would ruin most generic companies. As a result, few generic companies can risk going to market before a final judicial resolution of its patent invalidity and/or non-infringement claims. Thus, by refusing to bring suit immediately, brand companies create paralyzing uncertainty that allows these companies to continue selling drugs at monopoly prices while generic companies struggle

to obtain the certainty that they need to launch free from fear of patent infringement liability. This is not speculation on Apotex's part. Indeed, the negative impact that such tactics have on the generic industry and the public readily can be observed by considering the current situation surrounding the drug Accupril®, another Pfizer product.

As in the present case, Pfizer did not sue all ANDA applicants that sought to market a generic product before expiration of Pfizer's Orange Book-listed patents for Accupril®. Fearing that Pfizer would delay suit until they commercially marketed their drugs, ANDA applicants, like Apotex and Mutual Pharmaceutical Company, filed declaratory judgment actions against Pfizer in an attempt to obtain a decision that would allow them to launch without incurring infringement liability. But just as it did here, Pfizer moved to dismiss those declaratory judgment actions for lack of subject matter jurisdiction, arguing that Apotex and Mutual could not reasonably fear suit where Pfizer had not sued any subsequent ANDA applicants. After the dismissal of those suits, and just as Apotex and Mutual feared, Pfizer sued the first company (Ranbaxy Pharmaceuticals) to begin commercial marketing of a competing generic drug. (*Pfizer Inc. v. Ranbaxy Pharms. USA, Inc., et. al*, No. 05-620 (D.N.J.)). Pfizer obtained a preliminary injunction requiring Ranbaxy to pull its lower-priced generic Accupril® product from the market, thereby depriving the public of this product. And while several other companies have FDA approval to begin marketing their own generic Accupril® products,[5] they have not done so. Thus, brand companies like Pfizer have, in effect, created a new "*de facto*" exclusivity period in direct contravention of Congress' express intent.

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[5] *See* FDA's list of finally-approved quinapril ANDAs at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=QUINAPRIL%20HCL.

2. Congress enacts the MMA to prevent brand manipulation and to expedite generic market entry.

Faced with staggering increases in the cost of prescription drugs, and concerned about patentee manipulation, Congress enhanced the Declaratory Judgment provisions by enacting the MMA. The declaratory judgment provisions of the MMA are, in fact, a critical component of Congress' new legislative scheme because they are the only effective way to get generic drugs into the hands of patients fast in circumstances where delay better serves the economic interests of a patentee than immediate commencement of an infringement action. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1072-73 (D.C. Cir. 1998).

The Federal Circuit's decision entirely undermines Congress' attempt to prevent further gaming of the system by brand companies, such as Pfizer. Indeed, Pfizer's transparent "gaming" of the system here, and with Accupril®, is precisely the "sad and saddening" situation that Congress designed the Declaratory Judgment Act and MMA to remedy. *See Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 734-35 (Fed. Cir. 1988); (App. 35a (recognizing that "[s]ubsequent ANDA applicants suffer a real and defined harm when uncertainty exists as to their rights to manufacture and sell a generic drug product free from infringement allegations. By permitting generic companies to bring declaratory judgment claims, Congress has not sought to create a hypothetical injury-in-fact; it has simply recognized the harm that exists absent such relief.") (Mayer, J. dissenting)).

By running afoul of Congressional intent, the Federal Circuit's decision also runs contrary to other precedent from this Court. *See Miller v. French*, 530 U.S. 327, 328 (2000) (citing *Sinclair Ref. Co. v. Atkinson*, 370 U.S. 195, 215 (1962) for proposition that "where, as here, Congress has made its intent clear, this Court must give effect to that

intent"); *Flora v. United States*, 357 U.S. 63, 65 (1958) (stating that "[i]n matters of statutory construction the duty of this Court is to give effect to the intent of Congress, and in doing so our first reference is of course to the literal meaning of words employed").

This Court should hear Teva's Petition in order to reverse the Federal Circuit's ruling, which, without question, runs contrary to Congress' intent when enacting both Hatch-Waxman and the 2003 MMA declaratory judgment provisions. Absent review by this Court, both the generic pharmaceutical industry and the American public will suffer.

CONCLUSION

For all these reasons, the Court should *grant* Teva's Petition.

Respectfully submitted,

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September 7, 2005

Supreme Court, U.S.
FILED
SEP 7 - 2005
OFFICE OF THE CLERK

(6)

No. 05-48

IN THE
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TEVA PHARMACEUTICALS USA, INC.,

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v.

PFIZER, INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF AARP AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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BRIEF OF AARP AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

STATEMENT OF INTEREST[1/]

AARP is a nonprofit, nonpartisan membership organization of more than 35.5 million persons aged 50 and

[1/] No counsel for any party authored any portion of this brief. No persons other than *amicus curiae*, their members, or their counsel have made a monetary contribution to the preparation and submission of this brief. The written consent and non-opposition of the parties have been filed with the Clerk of the Court pursuant to Supreme Court Rule 37.3.

older, dedicated to addressing the needs and interests of older Americans. AARP works to ensure that everyone has access to needed health care and prescription drugs, but prescription drug treatments are particularly important to older persons who have the highest rate of prescription drug use. Persons over 65, although only 13 percent of the population, account for 34 percent of all prescriptions dispensed and 42 cents of every dollar expended on prescription drugs. Families USA, *Cost Overdose: Growth in Drug Spending for the Elderly, 1992-2010* at 2 (July 2000) *available at* http://www.familiesusa.org/site/DocServer/drugod.pdf?docID=726.

Prescription drug spending has skyrocketed over the last decade and a half. Since 1990, national health expenditures on prescription drugs has quadrupled -from $40.3 billion to $179.2 billion in 2003. Centers for Medicare and Medicaid Services, National Health Expenditures Aggregate Amounts and Average Annual Percent Change, by Type of Expenditure: Select Calender Years 1980-2003 *at* http://www.cms.hhs.gov/statistics/nhe/historical/t2.asp. The rising costs of prescription drugs have left many older Americans unable to afford necessary medications.[2/] Access to generic drugs can help ameliorate the harm done by the high costs of prescription drugs, sparking AARP efforts at the state and national level to increase access to lower cost generic versions of drugs. AARP has filed *amicus curiae* briefs in prescription drug litigation related to access to

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[2/] Research shows that patients' response to the higher drugs costs is to reduce consumption. Jan Blustein, *Drug Coverage and Drug Purchases by Medicare Beneficiaries with Hypertension*, 19 Health Affairs 219, 228 (2000); Dana Gelb Safran et al., *Prescription Drug Coverage and Seniors: Findings From A 2003 Survey* Health Affairs (Web Exclusive) 157-58 (Apr. 19, 2004) (12.8% of all adults report not getting prescription drugs because of cost.)

generics in several Circuits, including the case below in the Federal Circuit, *Teva Pharmaceuticals, Inc. v. Pfizer*, 395 F.3d 1324 (Fed. Cir. 2005). AARP also filed an amicus in the recent case of *Merck KgaA v. Integra Lifesciences I, Ltd.*, _U.S._, 125 S. Ct. 2372 (2005)(involving patent infringement exception). AARP strongly supported inclusion of § 1101(a)(C), § 1101(b)(2)(D) and §1101(d) in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified at 21 U.S.C. § 355(j)(5)(C) with respect to abbreviated new drug applications, 21 U.S.C. § 355(c)(3)(D) with respect to new drug applications, and 35 U.S.C. § 271(e)(5) with respect to subject matter jurisdiction over patent disputes). Those provisions, among others designed to allow non-infringing drugs to come to market sooner, expressly permit a "civil action to obtain patent certainty" in the form of a declaratory judgement action when the patent holder or name brand manufacturer declines to initiate a patent infringement action. 21 U.S.C. § 355(c)(3)(D), (j)(5)(C).

AARP has a great interest in the Courts' jurisdiction over the question of whether the sale of generic versions of popular and expensive drugs would infringe a valid patent.[3/] It is in all consumers' interest to assure that patent disputes will be resolved expeditiously so that if there is no patent infringement, generic alternatives to brand name drugs will be available as soon as possible. For these reasons, AARP files this brief supporting Petitioner's request for certiorari.

[3/] With sales of $3.3 billion in 2003, Zoloft is one of the best selling drugs in the world. Pfizer, 2003 Financial Report at 7 *available at* http://www.pfizer.com/are/investors_reports/annual_2003/financial2003.pdf.

REASONS FOR GRANTING THE PETITION

A. The Federal Circuit's Decision Thwarts Congress' Intention to Stop Drug Companies from Exploiting Aspects of the Hatch-Waxman Act To Delay Generic Competition.

Title XI – "Access to Affordable Pharmaceuticals" of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 (MMA) is the first Congressional effort in many years to reign in a pattern of laws which have extended intellectual property protection to branded drugs, and which have delayed entry of affordable generic drugs:

> Over the past two decades, Congress has enacted a series of laws that have greatly increased the "effective patent life" enjoyed by brand name prescription drugs . . . . Considered individually, each of these laws offers a reasonable approach to stimulate pharmaceutical innovation and ensure broad access to new medications. Viewed collectively, the laws have conferred multiple and additive protection on prescription drugs.

Michie I. Hunt, *Prescription Drugs and Intellectual Property Protection: Finding the Right Balance Between Access and Innovation*, NIHCM Issue Brief at 1 (Aug. 2000) *available at* http://www.nihcm.org/prescription.pdf. The "average effective patent life of many new drugs has increased by at least 50 percent between the early 1980s and today." *Id.* "Lengthening patent terms and providing other forms of [intellectual property protection] to branded drugs delay the entry of generic drugs, which are usually far less expensive." *Id.* at 3.

Congress began to recognize that drug companies were using provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act) in ways never intended, which resulted in delaying consumers' access to affordable medications.[4/] The Hatch-Waxman Amendments aimed to strike a careful balance of encouraging innovation by brand name manufacturers while still fostering generic competition in order to control escalating drug expenditures. But some companies gamed the law in ways which actually stifled competition. Congress' answer to restore the balance was to pass Title XI – "Access to Affordable Pharmaceuticals" of the MMA.

First, in § 1101, Congress limited the stay of generic competition granted to name brand manufacturers when generic manufacturers filed Abbreviated New Drug Applications (ANDAs) with the FDA. It was limited to a single 30 month period following the instigation of litigation to determine patent validity, thereby "allowing lower-priced generic products to enter the market more quickly." Joint Explanatory Text to the MMA Conference Agreement, H.R. Conf. Rep. No. 108-391, at 836 (2003) *reprinted in* 2004 U.S.C.C.A.N. 2187. This was to prohibit the successive stacking of 30 month stays which some patent holders utilized to delay approval of generic versions of "several blockbuster drugs and cost consumers billions of dollars."

[4/] *See* Testimony of Timothy J. Muris, Chairman Federal Trade Commission, before the United States Senate Committee on the Judiciary, *The FTC Study on Barriers to Entry in the Pharmaceutical Marketplace* (June 17, 2003) (presenting the findings of its report, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002)); David Gross, AARP Public Policy Institute, *Generic Drugs*, AARP Issue Brief at 15 (2003) *available at* http://research.aarp.org/health/ib61_generic.html.